

**REMARKS**

**Claims status and formal matters**

Claims 1-6, 8-32, 34-38, 41-75 are pending. Claims 1, 4, 8, 43, 44, 45, and 61 are currently amended. Claims 11-24, 46-60, 62-75 have been withdrawn by the Examiner. Claims 39 and 40 are cancelled without prejudice to applicants' ability to pursue the subject matter of these claims in a divisional or a continuation application.

Claims 45 and 61 are listed as allowed. Claims 45 and 61 are also listed as rejected under 35 U.S.C. §112 ¶1—Enablement Rejection.

Support for current amendments can be found throughout the specification and specifically in paragraphs [0009], and [0046] of the application as published.

Previous rejections under 35 U.S.C. §102 and §103 have been withdrawn by the Examiner.

**Rejections Under 35 U.S.C. §112 ¶1—Written Description Rejection**

The Examiner rejected claims 1-6, 8-10, 25-32 and 34-44 for failure to comply with the written description requirement. According to the Examiner, the terms "from 13 to about 30 consecutive nucleotides," as recited in claims 1-6, 8-10, 25-32, 34-38, "from 19 to about 30 consecutive nucleotides," as recited in claims 39 and 40, and "from 19 to about 28 consecutive nucleotides," as recited in claims 41 and 42, are not supported in the original disclosure.

Without conceding the correctness of the Examiner's rejection regarding the term "from 13 to about 30 consecutive nucleotides," as recited in claims 1-6, 8-10, 25-32, 34-38, applicants have amended claims 1, 4, 8, 43, and 44. Amended claims 1, 4, 8, 43, and 44 recite "19 to about 30 consecutive nucleotides."

Applicants respectfully traverse Examiner's rejection that the terms "from 19 to about 30 consecutive nucleotides," as recited in amended claims 1, 4, 8, 43, and 44, and "from 19 to about 28 consecutive nucleotides," as recited in claims 41 and 42, fail to comply with the written description requirement.

The law is well established that the purpose of the written description requirement is to ensure that the applicants were in possession, at the time of the filing, of the subject matter later claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1632-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Furthermore, the subject matter of the claim does not need to be described literally.

The Examiner asserts that according to *In re Smith*, 458 F.2d 1389, 173 USPQ 679 (CCPA 1971), “it cannot be said that such a subgenus is necessarily always implicitly described by a genus encompassing it and a species upon which it reads.” *Id.* at 1395.

Although the terms “10-30 consecutive nucleotides” and the claim language “19 to about 30 consecutive nucleotides,” or “19 to about 28 consecutive nucleotides” can be related as a genus, and subgenus, this classification overlooks the fact that the subject matter claims numeric range limitations. Written description analysis of numeric range limitations should account “which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure.” See MPEP 2163.05 (III).

Furthermore, the CCPA has noted that there is “an important practical distinction between broad generic chemical compound inventions, . . . , in which each compound within the genus is a separate embodiment of the invention, and inventions like that at bar, in which the range of solids content is but one of several process parameters. What those skilled in the art would expect from using 34% solids content in the concentrated extract prior to foaming instead of 35% is a different matter from what those skilled in the art would expect from the next adjacent homolog of a compound whose properties are disclosed in the specification.” *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90 (CCPA 1976). The specification of the Swiss application discussed in *In re Wertheim* disclosed a range of “25%-60%” along with specific embodiments of “36%” and “50%”. *Id* at 265. The *in re Wertheim* Court found that a claim limitation of “between 35% and 60%” was supported by the specification and met the written description requirement. *Id.* The Court stated that “. . . in light of the description of the invention as employing solids contents within the range of 25-60% along with specific embodiments of 36% and 50%, we are of the opinion that, as a factual matter, persons skilled in the art would consider

processes employing a 35-60% solids content range to be part of appellants' invention . . .

.” *Id* at 265. Thus, a numerical range with specific embodiments in this range, can support a sub-range which does not include embodiments outside of the originally described range.

The facts of *In re Wertheim*, 541 F.2d 257 are apposite to the instant application. The *In re Wertheim* analysis of how a numeric range, and specific embodiments within that range, provide written description is pertinent to how the instant description of a numeric range of 10-30 consecutive nucleotides, and description of specific embodiments within that range, as disclosed in the instant application, provide written description for sub-ranges of “from 19 to about 30 consecutive nucleotides” and “from 19 to about 28 consecutive nucleotides.”

As the Examiner correctly points out, the specification describes a range of “10-30 consecutive nucleotides of at least one of the following: (a) the N gene region of the SARS-associated coronavirus genome; and (b) the 3' non-coding region of the SARS-associated coronavirus genome.” (See for example paragraph [0009]). Applicants note that the 3'-non-coding region and a portion of the N-gene region are depicted in SEQ ID NO:1 and SEQ ID NO: 43.

Furthermore, the specification describes multiple embodiments of nucleic acids within the range of 10-30 consecutive nucleotides. For example, the specification discloses nucleic acids sequences: of 19 consecutive nucleotides (SEQ ID NO: 11); of 20 consecutive nucleotides (SEQ ID NOS: 8, 14, 15); of 21 consecutive nucleotides (SEQ ID NOS: 2, 4, 25, 25); of 22 consecutive nucleotides (SEQ ID NOS: 10, 12); of 23 consecutive nucleotides (SEQ ID NOS: 5, 9); of 24 consecutive nucleotides (SEQ ID NOS: 3, 6, 7); of 25 consecutive nucleotides (SEQ ID NO: 16); and of 28 consecutive nucleotides (SEQ ID NO: 13).

Much like the description of the application discussed in *In re Wertheim*, the instant specification discloses a numeric range, “10-30 consecutive nucleotides” and several specific embodiments within that range. Thus, the instant specification provides a written description for a sub-range such as “19 to about 30 consecutive nucleotides” or

“19 to about 28 consecutive nucleotides” as recited in the amended claims. Indeed, the lower limit, 19 nucleotides, of the claimed range is a specific example provided in the specification. The upper limit of the range, 30 nucleotides, is disclosed as the upper limit specifically. A skilled artisan would consider that because the specification discloses a nucleic acid from the range of “10-30 consecutive nucleotides,” and numerous specific examples of nucleic acids within this range, the specification also discloses a sub-range such as “19 to about 30 consecutive nucleotides” or “19 to about 28 consecutive nucleotides.”

Furthermore, the term “about” is inherently disclosed in the application as filed. In addition to the range of 10-30 consecutive nucleotides as disclosed in paragraphs [0009] and [0011], the specification discloses a nucleic acid sequence which has 28 nucleotides, the nucleic acid sequence referred to as SEQ ID NO: 13. Therefore, the specification discloses a range which upper limit is about 30 nucleotides.

The burden of showing that the claimed invention is not described in the specification rests on the Examiner. In the outstanding Official Action, the Examiner has not provided any specific reasons why the claimed invention is not described in the specification. The Examiner essentially argues that there is no *ipsis verbis* support for the terms “from 13 to about 30 consecutive nucleotides of SEQ ID NO:43,” as recited in claims 1-6, 8-10, 25-32, 34-38, “from 19 to about 30 consecutive nucleotides of SEQ ID NO:43,” as recited in claims 39 and 40, and “from 19 to about 28 consecutive nucleotides of SEQ ID NO:43,” as recited in claims 41 and 42. Such arguments, without a clear reason why the invention is not described in the specification are not sufficient. *See, In re Wertheim*, at 265. In view of the foregoing, applicants respectfully request withdrawal of the rejection for lack of written description.

#### **Rejections Under 35 U.S.C. §112 ¶1—Enablement Rejection**

The Examiner rejected claims 1-6, 8-10, 25-32, 34-45, and 61 for lack of enablement. According to the Examiner, the specification while being enabling for “the” sequence consisting of 13 to about 30 consecutive nucleotides of SEQ ID NO:43 or “the” sequence consisting of SEQ ID NO:2, is not enabling for “a” sequence consisting of 13 to about 30 consecutive nucleotides of SEQ ID NO:43 or “a” sequence consisting of SEQ

ID NO:2. The Examiner alleges that the terms “a sequence” or “a nucleic acid” as recited in claims 1-6, 8-10, 25-32, 34-45, and 61 can be interpreted as comprising the full length SEQ ID NO or any portion thereof. The Examiner further alleges that somehow the claims encompass nucleotide sequences that are smaller than 13 to about 30 consecutive nucleotides of SEQ ID NO:43 or the full length SEQ ID NO:2, for example a nucleic acid sequence such as a trinucleotide.

Applicants thank the Examiner for the suggestion to amend the rejected claims to recite “A synthetic nucleic acid which has the sequence . . .” In view of the Examiners suggestion, applicants have amended claim 45 to recite “A synthetic nucleic acid which has the sequence consisting of SEQ ID NO: 2.” Claim 61 is also amended to recite “the nucleic acid of SEQ ID NO:2.”

Applicants respectfully traverse the Examiner’s enablement rejection, and suggestion for an amendment of claims 1-6, 8-10, 25-32, 34-44. Amended claims recite “19 to about 30 consecutive nucleotides,” or “19 to about 28 consecutive nucleotides.” The recitation “A synthetic nucleic acid which has a sequence consisting of from 19 to about 30 consecutive nucleotides of . . .” is commensurate with the scope of the claims. The claims encompass any one of a number of different synthetic nucleic acids, wherein each synthetic nucleic acid has any sequence “from 19 to about 30”, or “from 19 to about 28” consecutive nucleotides selected from the longer nucleic acid sequence represented as SEQ ID NO:43 (as recited in claim 1, for example), or selected from the longer nucleic acid sequence that is complementary to SEQ ID NO:43 (as recited in claim 4, for example).

Applicants also traverse the Examiner’s rejection that the claims, which recite limitations of “19 to about 30 consecutive nucleotides,” or “19 to about 28 consecutive nucleotides” encompass a trinucleotide, as alleged by the Examiner. The terms “19 to about 30 consecutive nucleotides,” or “19 to about 28 consecutive nucleotides” recite specific ranges of nucleic acid length, which ranges do not encompass a nucleic acid sequence which is shorter than 19 nucleotides or longer than 30, or 28 nucleotides, respectively. Thus, the limitations “19 to about 30 consecutive nucleotides,” or “19 to about 28 consecutive nucleotides” do not include nucleic acids sequences which length is

outside of the recited range. In view of the foregoing, applicants respectfully request withdrawal of the rejection.

Conclusion

For the reasons stated above, applicants request that the Examiner withdraw the grounds for rejection and allow the pending claims to proceed to issue. If the Examiner has any questions, she is invited to call the undersigned attorney.

Applicants request the courtesy of a telephonic interview with the Examiner.

Authorization is given to apply any charges that may be due, or any credits owed, to Deposit Account No. 08-0219.

Respectfully submitted,



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